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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/325,278

10/26/1994

LARS BJORCK

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01/29/2002

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EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 01/29/2002

39

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/325,278

Applicant(s)

BJORCK ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 14-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment*

1. Applicants' amendment filed September 28, 2001 is acknowledged and has been entered. Claim 20 has been canceled. Claims 14, 16 and 17 have been amended. Claims 14-19 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment and/or comments set forth in the amendment, with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The disclosure is objected to because of the following informalities: the specification at page 11—the last sentence on this page should be deleted since the figure descriptions have been moved to a different section of the specification. This statement makes no sense on page 11. The specification should not refer to specific claim numbers and language since the claim may be canceled or amended during the course of prosecution.  
Appropriate correction is required.
4. The disclosure is objected to because of the following informalities: there are certain nucleotide and/or amino acid sequences that do not have a sequence identifier (SEQ ID NO: \_). See for examples pp. 12, 18 and 19.

Appropriate correction is required.

5. The Kastern/Bjorck/Sjobring Declaration under 37 CFR 1.132 filed September 28, 2001 is sufficient to overcome the rejection of claims 14, 18 and 19 based upon 102(a) anticipation of Kastern et al (1992).

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14, 18 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 4,876,194 for the reason set forth in the last Office Action.

Applicants argue the rejection should be withdrawn in view that claims 1-14 of U.S. Patent No. 4,876,194 does not teach the sequence. Applicants' arguments

are not sufficient to obviate the rejection. It is reasonable to conclude protein L as set forth in the issued patent is the same, or in the alternative an obvious or analogous variant of protein consisting of SEQ ID No. 1 as recited in the instant application since they have the same properties (useful as kit, useful as pharmaceutical composition, bind light chains of immunoglobulins, and from *P. magnus* strain 312). Mere discovery that claimed composition possesses property not disclosed for prior art does not *alone* defeat prima facie case of obviousness and it is *not* necessary in order to establish prima facie case, to show both structural similarity between claimed and prior art compound *and* suggestion in, or expectation from, prior art that claimed compound will have same or similar utility as one newly discovered by applicant. See In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990).

For the reasons set forth above and in the last Office Action said rejection is maintained.

6. Claims 15-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 4,876,194 in view of Guss et al. (WO 87/05361)(Art Cited by Applicants in the IDS) and Kastern et al. (1990) (Infection and Immunity 58(5): 1217-22 5/90) (Art Cited by Applicants in the IDS) for the reason set forth in the last Office action.

Applicants' argument is set forth above. For the reasons set forth above and in the last Office Action said rejection is maintained.

Applicant's arguments filed October 12, 1999 have been fully considered but they are not persuasive. Applicants have asserted that obtaining the sequence of the L protein and identification of particular domains that bind immunoglobulin light chain is unusually difficult. However, Applicants have not set forth any evidence of record to support such an assertion. The rejection is maintained.

7. Claims 14, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 255 497 (Art Cited by Applicants in the IDS) or US Patent No. 4,876,194 ('194) (Art Cited by Applicants in the IDS).

The teachings of both references have been set forth in previous Office Actions, see paper number 14. The references teach the protein L and that the protein binds the light chains of immunoglobulins as claimed by Applicants except for the sequence. However, the mere discovery of a claimed sequence does not distinguish over the prior art if the prior art disclose other characteristics of the claimed invention. It is noted that the proteins of the cited prior art references were not characterized by the references as having a specific amino acid sequences. However, the mere discovery of an amino acid sequence, molecular weight or other characterizing features of a protein, which protein is taught by the prior art, imparts neither novelty nor unobviousness to the protein. Further, given that the protein(s) was known in the prior art, one of ordinary skill in the art would have been motivated to identify the amino acid sequence, molecular weight and whether or not the protein is glycosylated since proteins are routinely characterized in this manner. Therefore, the proteins of the reference appear to be consistent with those claimed with the various identifying characteristics

inherent in them. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Since the Patent Office does not have the facilities for examining and comparing applicants' proteins with the proteins of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed proteins and the proteins of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants have asserted that it was unusually difficult to obtain the amino acid sequence. However, such assertions should be made in the form of a declaration with references to support this assertion of unusual difficulty.

8. It is noted that rejections set forth in paragraphs 5-7 are maintained for the reasons of record. The Sjobring Declaration under 37 CFR 1.132 filed September 28, 2001 is insufficient to overcome the rejection of claims 14-19 based upon under the judicially created doctrine of obviousness-type double patenting as being unpatentable or based upon 103 obviousness as set forth in the last Office action. The declaration asserts that a different system had to be used (ligating Taq1 DNA fragments into the M13 system) to get the sequence and

that they are described in Kastern et al (1992). However, the method (ligating Taq1 DNA fragments into the M13 system) asserted to have been used by Applicants to overcome these unusual difficulties are not set forth in the specification nor the pending claims. Methods for determining the sequences are not set forth in the claims. If Applicants are relying on Sambrook et al or Sanger et al to teach the different method, then it would appear that it is not difficult if the system is already known and taught. With regard to declaration paragraph 2 (ii) (b), removing contaminants from the protein L preparation is also within the knowledge of a skilled artisan and not unusually difficult.

9. Claims 16, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of the various domains and the SEQ ID NO: 1 and 3. Applicants should define amino acid sequence position in the SEQ ID NO the set forth the domains (the various domains set forth in claim 16).

This rejection is maintained for the reasons of record. It is noted that Applicants have amended claim 16 to recite the amino acid (for example C1 amino acid 303-357). However, it is not clear if all (parts (i)-(iv) of claim 16) of these domains (defined range of amino acids) are in SEQ ID NO: 3 as claim 17 recites. Clarification is requested in order to do an appropriate sequence search.

10. No claims are allowed.



11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

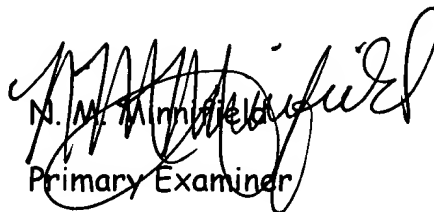
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



M. M. Mirmiran  
Primary Examiner

Art Unit 1645

January 15, 2002